

### **REMARKS**

Reconsideration of this application and entry of this Amendment is respectfully requested. Claim 17 has been amended to correct the antecedent basis issue. No new matter has been added.

### **Objections to the Specification/Drawings and Claim 17**

Examiner objected to the Title of the application on the grounds that it is not descriptive. Although Applicants respectfully disagree with Examiner's characterization of the title as nondescript, the title of the application has been amended herein to more clearly describe the invention and, thereby, overcome this objection.

Examiner objected to the specification for typographical errors relating to the reference characters. The specification has been amended herein to correct the errors. Reference character "300" has been added to Figures 4 and 5.

Figures 1-5 are prior art and have now been labeled accordingly. Replacement drawing sheets are being submitted herewith. Furthermore the specification has been amended to more clearly describe the nature of these figures.

Examiner has objected to claim 17 as lacking antecedent basis. Claim 17 has been amended herein to correct the problem. No new matter has been added.

### **Rejections under 35 U.S.C. §102(b)**

Claims 1, 7, 11, and 17-19 stand rejected as anticipated by Howard (EP pub. # 0 837 320), hereinafter “Howard”. For at least the reasons set forth below, the rejections are respectfully traversed.

Contrary to Examiner’s assertion in paragraph 11 of the present office action, Howard does not disclose an apparatus for verifying proper operation of an optical inspection machine. The present claimed invention can be viewed as a faux urine strip<sup>1</sup> that acts as an experimental control. The claimed verification strip has colored pads<sup>2</sup> that *simulate* the color of reacted reagent pads at a predetermined analyte concentration as they would appear on a real urine strip. Unlike a real urine strip, however, the color of the pads on the strip of the claimed invention are fixed and do not depend on analyte concentration. In fact, they are not exposed to the sample at all. Accordingly, the color of the pads do not vary, hence their function as a control.

The claimed strip allows a technician to test whether the optical inspection machine is reading color correctly. When this claimed strip is inserted into the optical inspection machine and read, a technician would expect a properly functioning optical inspection machine to return a value representing the predetermined concentration of analyte. If a different value is returned, then it can be inferred by the technician that

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<sup>1</sup> Please note that the term “urine strip” used herein was chosen as an example for clarity. The invention covers both reagent strips and reagent cassettes (See specification page 8, paragraph 40 et seq.).

<sup>2</sup> Called “segments” in the claims

there is a problem with the inspection machine since the control did not return the expected value. In other words, if the optical inspection machine does not accurately read the color of the pads of the control strip, then there must be a problem with the machine.

The Howard reference has nothing to do with a control for verifying the proper operation of an optical inspection machine. The Howard reference instead discloses a barcode-type color indicator ("coded sequence") on a *real* urine test strip that functions to pass information to the optical inspection machine about the real test strip (See Howard Column 2, paragraph 6). Perhaps it could be said that Howard is "verifying" the type of test strip, but certainly there is no disclosure or teaching in Howard that relates to verifying proper *operation of the machine*, that is, whether the machine is operating properly. The colored marker fields in Howard do not "simulate" reacted reagent pads at known concentrations of analyte as in the claimed invention. In fact, the colored marker fields of Howard must differ from the color of the reagent pads so that the receiver can differentiate between the reagent pad and the marker (See Howard column 3, lines 1-9). Accordingly, Howard does not anticipate the claimed invention. Reconsideration and withdrawal of this ground of rejection is respectfully requested.

#### **Rejections under 35 U.S.C. §103(a)**

Claims 8, 12-16, 20, 21, and 24-30 stand rejected as obvious over Howard. Claims 2-6 and 22 stand rejected as obvious over Howard. Claims 9, 10, and 23 stand

rejected as obvious over Howard in view of Matzinger et al. (6,168,957), hereinafter "Matzinger". For at least the reasons set forth below, the rejections are respectfully traversed.

All the rejections above rely on Howard as the primary reference to teach the basic claimed invention of an apparatus or method for verifying proper operation of an optical inspection machine. However, as explained above, the invention described in Howard is unrelated to the claimed invention. Howard does not teach or suggest the claimed invention. Specifically, Howard fails to teach or suggest: 1) an apparatus for verifying proper operation of an optical inspection machine and 2) a row of colored segments that *simulate reagent pads containing known types of analytes at known concentrations*. Furthermore, Howard teaches away from this second point by requiring that the marker field be differentiated from the test field, as explained above. Since none of the secondary references teach or suggest an apparatus or method for verifying proper operation of an optical inspection machine as claimed, the rejection under 35 U.S.C. §103(a) is improper and should be withdrawn.

## **CONCLUSION**

In view of the above arguments and amendments to the claims it is respectfully submitted that this application is now in condition for allowance and such favorable action is respectfully requested.

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Respectfully submitted,

A handwritten signature in black ink, appearing to read "Noam R. Pollack", with a long horizontal flourish extending to the right.

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